K031962

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
***NexGen* Trabecular Metal Tibial Cone Augments**

Submitter Name And Address:	Implex Corp. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818-1800
Fax Number:	(973) 829-0825
Date Prepared:	October 9, 2003
Device Trade Name:	*NexGen* Trabecular Metal Tibial Cone Augments
Device Common Name:	Knee System Augments
Classification Number and Name:	21 CFR § 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The *NexGen* Trabecular Metal Tibial Cone Augments are designed to be used in conjunction with Zimmer Inc.'s *Legacy®* Stemmed Tibial Bases (LCCK) and Rotating Hinge Knee (RHK) tibial components. The subject devices are used to address proximal tibial cavitary defects encountered when implanting either of these two systems. The augments are manufactured from Trabecular Metal and have tapered posterior, medial and lateral walls. The periphery of the inferior surface is smaller than that of the superior surface. The augments are hollow such that they are to be filled with bone cement, and allow for placement of the stem and/or keel of the associated tibial base plate. Fixation of the augment to the tibial baseplate is accomplished by using bone cement. The inferior surface of the LCCK and RHK tibial baseplates must be cemented to bone.

The Trabecular Metal Tibial Cone Augments are for cemented use along the bone in the USA, and for cementless or cemented use along the bone outside the USA.

510(k) Summary (Continued)

Indications for Use:

The *NexGen* Trabecular Metal Tibial Cone Augments are indicated for use in the reconstruction of bony defects in knee reconstruction due to severe degeneration, trauma, or other pathology of the knee joint, and in the revision or salvage of failed, previously reconstructed knee procedures and implants. The Trabecular Metal Tibial Cone Augments are for cemented use only in the USA, and for cementless or cemented use outside the USA.

Device Technological Characteristics and Comparison to Predicate Device:

A comparison of device technological characteristics and properties demonstrates that the device is substantial equivalent to the cited predicate devices.

Performance Data:

Testing of the subject devices were not performed. Previous testing of Trabecular Metal and Trabecular Metal devices support a determination of substantial equivalence. An engineering analysis was provided to support this (reference Appendix A of the addendum.

Conclusion:

The *NexGen* Trabecular Metal Tibial Cone Augments are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2004

Ms. Marci Halevi
Manager of Regulatory Affairs
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K031962
Trade/Device Name: NexGen Trabecular Metal Tibial Cone Augments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: October 9, 2003
Received: October 10, 2003

Dear Ms. Halevi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031962

Device Name: The *NexGen* Trabecular Metal Tibial Cone Augments

Indications For Use:

The *NexGen* Trabecular Metal Tibial Cone Augments are indicated for use in the reconstruction of bony defects in knee reconstruction due to severe degeneration, trauma, or other pathology of the knee joint, and in the revision or salvage of failed, previously reconstructed knee procedures and implants. The Trabecular Metal Tibial Cone Augments are for cemented use only in the USA, and for cementless or cemented use outside the USA.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR... Over-The-Counter Use _____

(Optional Format 1-2-96)

for Mark N Milhous

Division Sign-Off
Division of Cardiovascular, Respiratory, Restorative and Neurological Devices

510(k) Number K031962